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EXAMINER	
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ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,842	CHALIFOUR ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-56,58-64 and 66-109* is/are pending in the application.

4a) Of the above claim(s) *49,50,52-55,58-60,62-64,67 and 69-103* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-48,51,56,61,66,68 and 104-109* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *46-56,58-64 and 66-109* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2000* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9,10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS submissions 14, 15* .

DETAILED ACTION

1. The preliminary amendment filed 9-17-01 has been entered and has been fully considered. It is noted that the following entry as directed appears to be in error. Applicants appear to have inadvertently directed entry to p. 10, line 30-p. 13, line 10 where entry should have been directed to p. 10, line 24-p. 12, line 25. The entry cancels text. The amendments filed 4-15-02, 6-21-02 and 10-4-02 have been entered and have been fully considered.

2. Claims 1-45, 57 and 65 are canceled. Claims 46-56, 58-64 and 66-109 are pending.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: The oath contains reference to 60/168,594 to which applicants appear to be claiming priority. However, the box for claiming priority is not checked and thus the oath does not clearly claim benefit or acknowledge the duty to disclose material as required. For these reasons the priority claim is not perfected and a new oath should be submitted which corrects such deficiencies. As the priority claim has not been perfected the effective filing date of the pending claims is the filing date of 11-28-00. Prior art is cited accordingly.

Election/Restriction

4. Applicant's election with traverse of Group I, claims 46-69, 93-98 and new claims 104-109 to the extent of methods of treating or preventing by administration with a

peptide of SEQ ID NO:27, wherein R' is N-terminal hydrogen and R" is C-terminal unsubstituted amino group, in Paper No. 17(4-15-02) is acknowledged. The traversal is on the ground(s) that the claims as amended have withdrawn the Markush group of different amyloid proteins, that the claims are drawn to all D-amyloid beta peptides, that restriction is proper only if the inventions are independent and distinct and that the peptides are members of the same superfamily of peptides that induce an immune response to at least one region of the beta amyloid peptide. Applicants submit that all claims of the elected group read on the elected invention.

This is not found persuasive. Although the claims have been amended to narrow the scope to beta amyloid peptides, the claims remain drawn to peptides that differ in primary structures (sequence) as recited in the claims and as evidenced by their different sequence identifiers. The peptides lack common structure and accordingly are capable of different uses, effects and functions. A search for any single sequence would not reveal all relevant art to any other sequence. Further, a reference against any particular peptide would not necessarily be a reference to any other with respect to 35 USC 102 or 103. Therefore the peptides are not proper species and lack unity of invention in accordance with MPEP 803.02 as they lack common structure. Moreover, it is noted that the inventions need only be independent or distinct in accordance with MPEP 803, see also discussions of the terms in MPEP 802.01-02. Nevertheless, the separately defined peptides are both independent and distinct as set forth. Applicant's assert that all claims of the elected group (claims 46-69, 93-98 and 104-109) read on the elected invention and species. However, the claims are limited to the extent of the

elected peptide of SEQ ID NO:27 and wherein substituents of R' (N-terminal) is hydrogen and R"(C-terminal) is unsubstituted amino group. Thus, claims 49-50, 52-55, 58-60, 62-64, 67, 69, and 93-98 are withdrawn as being drawn to non-elected groups and species. As to claim 50 and 59-60, the elected species is not of an acid or base functional group, salt or ester form. The Examiner does not recognize such with respect to a peptide with N-terminal hydrogen or C-terminal unsubstituted amino. Thus, the claims recite non-elected species substituents. As to claims 52-55, 62-64 and 69, the recitations recite amino acid sequences other than elected SEQ ID NO:27. As to claims 49 and 58, the elected substituents are not of alkyl or aromatic groups. As to claim 67, the recitation is to the non-elected disease of cerebral amyloid angiopathy. As to claims 93-98, the examiner cannot discern whether or not SEQ ID NO: 27 is a peptide that interacts with at least one region of an IAPP peptide because the claim fails to delineate that which is IAPP or that SEQ ID NO:27 is capable of binding it. The literature appears to designate islet amyloid pancreatic protein as IAPP but the examiner cannot find any reference to SEQ ID NO:27 binding it. Thus, the claim is deemed to be non-elected absent clarification of what IAPP is intended to represent and evidence that SEQ ID NO:27 interacts with it.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 49-50, 52-55, 58-60, 62-64, 67, 69-103 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

6. Claims 46-48, 51, 56, 61, 66, 68 and 104-109 are under examination.

Drawings

7. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 10-4-02 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance. Applicants should additionally note the corrections required by the draftsman as noted in the PTO-948 attached herewith.

Double Patenting

8. The Examiner notes the application of 09/867,847 filed by the same Applicant's as instant application. However, the examiner has been unable to obtain access to the case for the evaluation of potential double patenting issues. In a telephone inquiry with Applicant's representative, the Examiner was notified that the application is not being handled by the same firm/representative as instant case and thus Applicant's representative was also unable to provide a copy of the pending claims in the co-pending case or to speak to the subject matter claimed therein. It is noted by the Examiner that the co-pending case shares the same title as instant case and thus that the subject matter is presumed to overlap. As the claims in the co-pending case are unavailable at this time, the issue is deferred until the next office action on the merits during which time the Examiner should be able to obtain the co-pending case. No double patenting rejection is set forth herein. However, Applicant's representative is hereby informed of this outstanding issue and of the basis for statutory and nonstatutory double patenting rejections. Applicant's should attempt to review the co-pending application so as to avoid such issues.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Objections

9. Claims 46-48, 51, 56, 61, 66, 68 and 104-109 are objected to as reciting an

improper Markush Group. M.P.E.P. 803.02 states that:

Since the decisions in In re Weber, 198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention

exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.

In instant case the encompassed peptides differ substantially in structure and are capable of different use, with different modes of operation, different function and different effects and therefore lack unity of invention.

10. Claims 51, 56, 61, 66 and 68 are objected to for the use of the art recognized term amyloid-β peptide in a manner that is repugnant to the art. In particular the artisan recognizes amyloid-β peptide which is between 40-42 residues, see in particular specification at the paragraph spanning p. 2-3, as recognized for example in the art, see in particular IDS reference A3, column 2, lines 25-50. However, claims 51, 56, 61, 66 and 68 use the term where it references sequences which are deletion, insertion or substitution mutants and which vary substantially in length (both less than and greater than) from the art recognized form, see in particular SEQ ID NO's:1-48 and the peptide recitations of the claims.

11. Claim 51 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The objection above notes that particular sequences encompassed by claims 51 contain less than or other than those amino acids required by the art recognized recitation of amyloid-β peptide. In particular the independent claim requires amyloid-β peptide residues. However, claims 51 further broaden the scope of the claim to encompass peptides which are of fewer

amino acids, for example the elected invention (SEQ ID NO:27) of 10 residues, peptides with an unlimited (at least one) amino acid deletion, alternate sequences by substitution and peptides with an unlimited (at least one) amino acid insertion. Thus, the claims do not further limit the 40-42 residue amyloid-β peptide(s) but broaden the scope of the claims to encompass alternative peptides of variable sequence and length which are not properly dependent as they are not drawn to the required peptide structure of the parent claim, i.e., amyloid-β peptide.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 51, 56, 61, 66 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947).

MPEP 2173.05(a) states that:

While a term used in the claims may be given a special meaning in the description of the invention, generally no term may be given a meaning repugnant to the usual meaning of the term. In re Hill, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). However, it has been stated that consistent with the well-established axiom in patent law that a patentee is free to be his or her own lexicographer, a patentee may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings. Hormone Research Foundation Inc. v. Genentech Inc., 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990). Accordingly, when there is more than one definition for a term, it is incumbent upon applicant to make clear which definition is being relied upon to claim

the invention. Until the meaning of a term or phrase used in a claim is clear, a rejection under 35 U.S.C. 112, second paragraph is appropriate. It is appropriate to compare the meaning of terms given in technical dictionaries in order to ascertain the accepted meaning of a term in the art. In re Barr, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).

The term "amyloid-β peptide" in the claims is used by the claim to mean peptides of variable sequence and length while the art accepted meaning consistent with p. 2-3 of the specification is the recognized structure of the 40-42 residue β-amyloid precursor protein cleavage product as in IDS reference A3, column 2, lines 25-50. Thus the peptides referred to as amyloid-β peptides is indefinite as claimed because the artisan cannot discern the peptide residues which are required.

14. Claims 46-48, 51, 56, 61, 66, 68 and 104-109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46-48, 51, 56, 61, 66, 68, and 104-109 use the term "all-D" which is variably defined in the specification at p. 7, lines 32-33 to mean less than all, i.e., ≥ 75% etc. The term "all-D" in claims 46-48, 50-52, 53-56, 59-64, 66, 68, and 104-109 is used by the claim to mean less than all as set forth at p. 7, lines 32-33 while the art accepted meaning of "all" is every. Thus, the metes and bounds of the amino acids which are required to be D-amino acids is indefinite.

Claims 104-109 recite, "prevents and/or reduces." The claim is indefinite because the artisan cannot discern which elements are required to meet the claim limitations, both elements or merely one.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 46-48, 51, 56, 61, 66, 68 and 104-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over, Schenk et al., WO Publication No. WO 99/27944 published 10 June 1999, Alberts, 2nd Ed., Molecular Biology of the Cell, Garland Publishing, 1989, pp. 54, Tjernberg et al. (a), J. Biol. Chem 271(15):8545-8, April 12, 1996, Tjernberg et al. (b), J. of Biol. Chem 272(19):12601-65, May 9,1997, Soto et al., Biochem. & Biophys. Res. Comm., 226:672-680, 1996, Findeis et al.(a), 5,854204, filed March 14, 1996, issued Dec. 29, 1998 and Findeis et al.(b), 5,985,242, filed August 27, 1997, issued Nov. 16, 1999, Gross et al., US 5,002,872, issued March 26, 1991 and Isowa et al., US 4,116768, issued Sept. 26, 1978.

Schenk et al., teach β-amyloid peptides, and fragments thereof effective to evoke an immune response within the host against an amyloid plaque and which administration is effective to reduce amyloid plaque burden in brains exhibiting Alzheimer's type pathology, see in particular pp. 13-15 and 51-53. Schenk also teaches a method of preventing or treating a disease characterized by amyloid deposits in a patient comprising administering an agent effective to induce an immune response against a peptide component of an amyloid deposit in the patient, wherein the amyloid deposit comprises aggregated Aβ peptide, and wherein the immunizing peptide or agent is Aβ peptide, see in particular claims 8-23. Schenk additionally teaches that the immunogenic peptides can be expressed as fusion proteins with carriers, linked at the amino or carboxy terminus or may be modified or unnatural amino acids, see in particular p. 14-16 and 20, lines 33-37. The beta-amyloid peptides of Schenk comprise the peptide of SEQ ID NO:27 with N' terminal hydrogen (the natural formation of N' terminal amino acids), see in particular Alberts, pp. 54 exhibiting N'terminal hydrogen bonds. The treatment of a patient via Schenk is understood to include humans or other mammalian subjects, see in particular pp. 12, lines 25-27.

However, Schenk does not teach the peptide consisting of SEQ ID NO:27 which is all D with C' terminal un-substituted amino.

Tjernberg et al., teach the amino acids consisting of SEQ ID NO:27 useful for the inhibition of amyloid fibril formation and suggest its use as a peptide agent aimed at inhibiting beta amyloid amyloidogenesis in vivo, see in particular Tjernberg et al. (a), Abstract, Figure 2, Results and Discussion and Tjernberg et al. (b), Abstract, Figure 1,

Results and Discussion. Tjernberg et al. (b), teaches D-amino acid peptides effective for binding and inhibiting beta-amyloid fibril formation and note their advantage of protease-resistance and suitability for use as agents for the inhibition of amyloid fibril formation in vivo, see in particular Abstract, Results and Discussion.

However, Tjernberg does not teach the peptide of SEQ ID NO:27 which is all D with C' terminal unsubstituted amino.

Findeis et al., (a) and (b) are largely cumulative. Both references teach modulators of beta amyloid aggregateion including for inhibition of beta-amyloid aggregation in vivo and inhibition of amyloid related diseases such as Alzheimer's Disease, see in particular Summary of the Invention. Findeis et al., teach treatment of subjects with disorders associated with β-amyloidosis, particularly patients with Alzheimer's disease. The peptides may be all or partial D-amino acids as particularly directed in the '242 patent, see in particular Summary of the Invention and may also include modified groups at N' and C' termini, see in particular Tables I-VI. The amyloid peptides also include partial β-amyloid peptide sequences as disclosed in Tables I-VI and sequence listing of β-amyloid peptides, column 64 and paper copy columns 65-84. The peptide administration intrinsically induces an antigenic response as evidenced by Schenk above, absent factual evidence to the contrary.

Findeis et al. (a) and (b) fail to teach wherein the functional group at the C'terminus is unsubstituted amino.

Soto et al., further recognize the use of D-amino acids as inhibiting to beta amyloid aggregation and to provide the advantage of resistance to catabolism in the host for such pharmaceuticals, see in particular pp. 677-678, paragraph spanning.

US 5,002,872 and US 4,116,768 teach the recognition of the art of pharmaceutical preparation of C' terminal modified unsubstituted amino groups as protective groups for stabilization of the peptide compounds in vivo.

Thus, the artisan recognizes the treatment of Alzheimer's disease via administraion of immunogenic doses of beta amyloid peptides in vivo, and further recognizes the additionally advantageous properties of SEQ ID NO:27, not only for the induction of such a response as recognized by Schenk, but also for the additional properties of inhibiting amyloid fibril formation in vitro and it's suggested use in vivo for inhibiting amyloid plaue formation. Moreover the artisan recognizes amino terminal group hydrogen on naturally occuring peptides and C' terminal unsubstituted amino protective groups to stabilize such pharmaceuticals in vivo. Thus, the artisan understanding these principles would be motivated to produce the anti-amyloidogenic peptide of SEQ ID NO:27 in all D-amino acid conformation and with C' terminal protective group unsubstituted amino to provide treatment of Alzheimer's disease as recognized in the art via both it's immunogenic and anti-fibrillogenic properties. One of skill in the art would be specifically motivated to produce the peptide in D-amino acid conformation and with C' terminal protective groups based upon the art recognized teachings of greater stability of such molecules in vivo while retaining both anti-fibrillogenic and immunostimulatory properties. Such modification would be met with an

expectation of success by the artisan based upon the conservation of immunogenic and anti-fibrillogenic properties within the host while providing the advantages of a compound resistant to catabolism and decreased half-life. Thus, the cumulative reference teachings render the claimed invention obvious to the artisan at the time of filing.

Status of Claims

17. No claims are allowed.

18. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
December 26, 2002